SUMMARY OF THE ELAB PBMS WORKGROUP TELECONFERENCE SEPTEMBER 8, 1998

The Performance Based Measurement Systems (PBMS) workgroup of the Environmental Laboratory Advisory Board (ELAB) convened by teleconference on September 8, 1998, at 1 p.m. The meeting was led by its chair, Mr. Jerry Parr, using the distributed agenda. Action items are given in Attachment A. The list of participants is given in Attachment B. *The purpose of this meeting was to further refine the draft list of key elements of a PBMS*.

INTRODUCTION

Dr. Barton Simmons outlined his contact with the Methods and Data Comparability Board, a joint effort by the U.S. Environmental Protection Agency (EPA) and the U.S. Geological Survey (USGS) to harmonize measurement methods. This is anticipated to include a compendium of methods as well as an approach comparable to EPA's PBMS, with an initial demonstration and pilot project in the near future.

KEY ELEMENTS

Mr. Jerry Parr asked for comments on the draft key elements, in order. It was agreed that the explanatory text was essential material to be associated with each element.

Legal Defensibility

It was agreed that the credible evidence rule must be considered in development of this element, and that legal advice would be appropriate at this point. The issues of proprietary algorithms and the use of existing technologies in new ways was raised. Mr. Parr and Ms. Lara Autry agreed to request informal advice for the committee and Mr. Parr will summarize the responses.

Flexibility

It was noted that, in principle, PBMS extends beyond modified "standard" methods (e.g., new chromatographic column conditions), to the introduction of entirely new measurement technologies. Education of data users will be necessary to ensure the acceptability of PBMS methodology in compliance scenarios.

Innovation (EPA Approval)

Following discussion, it was agreed that the concepts of concern in this element are more relevant to obtaining EPA approval of a particular method, than to innovation, per se, so it was agreed to change the title appropriately. It was noted that, while some programs have a defined process for approving new methods, there is no agency-wide process that would apply to new methodology developed in response to PBMS. It was suggested that the Environmental Monitoring Management Council (EMMC) might have a role in the development and implementation of such an approval process.

Regulatory Development

Following a brief discussion, it was agreed that this element needs only minimal editorial changes.

Documentation

It was agreed that this element needs no further change.

Cost Effectiveness

Concern was expressed that an extreme interpretation of PBMS could lead to requirement of method validation for each sample, which would hinder development of new methods. It was agreed that the apparent intent related to the intended use of the data, and that validation should recognize this intent.

It was also noted that cost-effective reference materials will be needed to achieve cost-effective method validation under PBMS.

Regulatory Compliance

There was no further discussion on this element.

Consistency

There was no further discussion on this element.

Simplicity

Mr. Parr will incorporate some suggestions he received prior to this meeting. There was no further discussion on this element.

Clarity of Intent

There was no further discussion on this element.

Scientifically Sound and Relevant Validation Process

Discussion of this element focused on the issue of using a suitable matrix for the intended use of the data, that is, the regulatory requirement(s). It was noted that "poor data" may still be usable. For example, spike recovery corrections might be used.

Good Performance Criteria

This element was revised to focus more specifically on PBMS performance criteria.

Careful Implementation

Following discussion of the importance of this element, including definition of the issues of responsibility and accountability, Mr. Parr will draft words for this element.

NEXT ISSUES

The implementation plans of each EPA National Program Office will be reviewed as they become available. The Office of Water's plan, summarized in a public presentation, will be distributed to committee members for their review. Other plans will be reviewed as they become available.

Ms. Sylvia Labie informed committee members that the NELAC Quality Systems committee plans a face-to-face meeting in early November to discuss PBMS and related issues. Members of this committee are welcome to attend.

NEXT MEETING

Arrangements have been made for regular meetings at two-week intervals with the next meeting scheduled for September 22, 1998.

ACTION ITEMS ELAB PBMS WORKGROUP TELECONFERENCE SEPTEMBER 8, 1998

No.	Action Item	Date to be Completed
1	Mr. Jerry Parr and Ms. Lara Autry agreed to request informal advice on "legal defensibility" issues of PBMS.	
2	Key elements, as refined in this meeting, will be reviewed by committee members for clarity and accuracy.	
3	Mr. Parr will revise the draft elements for the committee's review.	
4	Committee members are to review the Office of Water PBMS Implementation Plan for the next meeting.	

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